Complete Summary

GUIDELINE TITLE

Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding. London (UK): National Institute for Clinical Excellence (NICE); 2004 Apr. 25 p. (Technology appraisal; no. 78).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Heavy menstrual bleeding (menorrhagia)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Obstetrics and Gynecology
Surgery

INTENDED USERS

Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assess the effectiveness and cost-effectiveness of fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding

TARGET POPULATION

Premenopausal women with heavy menstrual bleeding (menorrhagia)

INTERVENTIONS AND PRACTICES CONSIDERED

Fluid-filled thermal balloon and microwave endometrial ablation

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness (bleeding outcomes, premenstrual symptoms [PMS] related outcomes, dysmenorrhoea, anaemia/haemoglobin outcomes, patient satisfaction, quality of life, operation details, need for further surgery, adverse effects)
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Peninsula Technology Assessment Group, Universities of Exeter and Plymouth (see the "Companion Documents" field).

Search Strategy

Electronic databases were searched for published studies, recently completed and ongoing research. Appendix 4 of the assessment report shows the databases searched and the strategy in full. Bibliographies of articles were also searched for further relevant papers. Experts in the field and relevant industry bodies were also asked to provide information.

Inclusion and Exclusion Criteria

Systematic reviews, randomised controlled trials (RCTs), and controlled trials of microwave and thermal balloon endometrial ablation versus transcervical resection of the endometrium (TCRE), rollerball or TCRE and rollerball combined were included.

Systematic reviews and RCTs of first generation endometrial ablation (EA) techniques versus hysterectomy published after 1999 were included.

Studies were excluded if they were:

- Animal models
- Preclinical and biological studies
- Narrative reviews, editorials, opinions
- Non controlled studies
- Non English language papers
- Reports published as meeting abstracts only

Identification of studies was made in two stages, abstracts were examined independently for inclusion by two researchers. Disagreements were resolved by discussion. Then inclusion and exclusion of full text articles was made independently by two researchers and disagreements were resolved in discussion with a third.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction Strategy

Data were extracted by one researcher and checked by another. Actual numbers were extracted where possible and where necessary, analyses were repeated on an intention to treat basis from original data.

Quality Assessment Strategy

Relevant systematic reviews were assessed using the QUOROM checklist, which uses the following criteria:

1. The clinical question is made explicit.
2. The database and other information sources in detail and any restrictions.
3. Inclusion and exclusion criteria are specified.
4. The selection criteria, methods for validity assessment, data abstraction, study characteristics and quantitative data synthesis in sufficient detail to permit replication.
5. Characteristics of the included and excluded randomised controlled trials (RCTs), details of study design, interventions and outcomes are reported. How clinical heterogeneity was assessed is reported.
6. Principal measures of effects, method of combining results, handling of missing data, how statistical heterogeneity is assessed. Rationale for (and a priori) sub-group analysis, and any assessment of publication bias are provided.
7. A profile summarizing trial flow through the systematic review is shown.
8. Descriptive data for each included trial are given.
9. Agreement on the selection and validity assessment is reported.
10. Simple summary statistics and data needed to calculate effect sizes and confidence intervals in intent to treat analyses are given.

Assessments of quality of RCTs were performed using quality indicators as shown below. Due to the nature of the intervention, the presence of blinding to treatment received was not considered an appropriate measure of quality, although concealment of allocation and blind assessment of outcomes remain valid as quality markers.

Internal Validity

Trial characteristics:

1. Appropriate method of randomisation.
2. Blind assessment of outcomes.
3. Number of women randomised, excluded and lost to follow up.
4. Whether an intent to treat analysis is performed.
5. Whether a power calculation is done.
6. Timing, duration and location of study.

External Validity

Study participants:

1. Age and any other recorded characteristics of women in studies
2. Inclusion criteria
3. Exclusion criteria
4. Length of follow up

Generalisability was categorised as high, (detailed description of the exclusion criteria and patient group) medium (description of exclusion criteria and patient group) or low (no description of exclusion criteria or patient group.)

Interventions used:

1. Type of endometrial ablation technique and route of hysterectomy surgery
2. Endometrial thinning agents used.

Methods of Analysis

There was considerable clinical and methodological heterogeneity among studies included in the review. Quantitative synthesis through meta-analysis was therefore not undertaken.

Study results are tabulated and for outcomes where there are a multiple data points at the same follow up point and with similar methods of outcome measurement, these are illustrated using forest plots.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients, and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Only one published study was identified. Three economic analyses were made available to the Institute as part of manufacturers' submissions, and the Assessment Group developed its own model (see below). See Section 4.2 of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

Cost Effectiveness Model

A state transition (Markov) model was developed by the authors of the assessment report using Microsoft Excel. The structure was informed by clinical input. The model examines the progress of five hypothetical cohorts of women with heavy menstrual bleeding who are treated separately by thermal balloon, microwave, transcervical resection (TCRE) or rollerball endometrial ablation, or hysterectomy. The model takes the perspective of the National Health Service

(NHS) and calculates incremental cost utility between options. Details of the cost effectiveness model are provided in the assessment report.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Fluid-filled thermal balloon endometrial ablation and microwave endometrial ablation are recommended as treatment options for women with heavy menstrual bleeding in cases where it has been decided (by the woman and the clinician responsible for her treatment) that surgical intervention is appropriate for the management of the condition.
- For heavy menstrual bleeding, the choice of surgical treatment should be made jointly by the woman and the clinician responsible for treatment. The decision should be made after an informed discussion taking into account the desired outcome of the treatment (such as reduced menstrual bleeding or complete cessation of menstrual bleeding [amenorrhoea]), the relative benefits of all other treatment options and the adverse events associated with them, as well as the clinical condition, anatomical suitability and preferences of the woman.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Two randomised controlled trials (RCTs) of microwave endometrial ablation (MEA) and seven trials of thermal balloon ablation (TBEA) versus first generation

techniques were used to support the clinical effectiveness recommendations. One of the TBEA trials is a non-randomised controlled trial and the rest are RCTs.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of fluid-filled thermal balloon and microwave endometrial ablation techniques to reduce morbidity in premenopausal women with heavy menstrual bleeding

POTENTIAL HARMS

- Adverse events with second-generation endometrial ablation (EA) techniques such as thermal balloon endometrial ablation (TBEA) and microwave endometrial ablation (MEA) include uterine infection, perforation, visceral burn, bleeding, haematometra, laceration, intra-abdominal injury and cyclical pain.
- Women who do not respond to initial EA may require further ablations or, eventually, hysterectomy.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Thermal balloon endometrial ablation (TBEA) cannot be used on women with large or irregular uterine cavities because the balloon must be in direct contact with the uterine wall to cause ablation. Cavaterm is contraindicated for women whose uterine cavity is more than 10 cm long (from the internal os to the fundus), and Thermachoice for women whose uterine cavity is more than 12 cm long, and for those who have a latex allergy. TBEA is also contraindicated if classical caesarean section (vertical midline incision in the upper segment of the uterus) has been performed, or if other uterine surgery has left a scar where the uterine wall is less than 8 mm thick. The use of endometrial thinning agents before TBEA is not recommended.
- Microwave endometrial ablation (MEA) is contraindicated if classical caesarean section (vertical midline incision in the upper segment of the uterus) has been performed, or if other uterine surgery has left a scar where the uterine wall is less than 8 mm thick.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

- All clinicians who care for women with heavy menstrual bleeding (HMB) should review their current practice and policies to take account of the guidance
- Local guidelines, protocols or care pathways that refer to the care of women with HMB should incorporate the guidance.
- To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
    - A woman with HMB who has decided with the clinician responsible for treatment that surgical intervention is appropriate for the management of the condition is offered thermal balloon endometrial ablation (TBEA) and microwave endometrial ablation (MEA) as treatment options, if they are not contraindicated.
    - The woman and the clinician responsible for treatment decide jointly on the choice of surgical treatment for HMB after an informed discussion.
- Local clinical audits on the care of women with HMB could also include measurement of compliance with accepted clinical guidelines or protocols.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding. London (UK): National Institute for Clinical Excellence (NICE); 2004 Apr. 25 p. (Technology appraisal; no. 78).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Apr

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2004 Apr. 2 p. (Technology appraisal 78). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Microwave and thermal balloon endometrial ablation versus traditional methods for heavy menstrual bleeding. Assessment report. Peninsula Technology Assessment Group, Wessex Institute for Health Research and Development; 2003 Jan. 189 p. Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0459. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the original guideline document.

PATIENT RESOURCES

The following is available:

- Fluid-filled thermal balloon and microwave endometrial ablation techniques for heavy menstrual bleeding. Understanding NICE guidance - information for women with heavy menstrual bleeding, and the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2004 Apr. 10 p. (Technology appraisal 78).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0460. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on March 9, 2006.

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